

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ACORDA THERAPEUTICS, INC. and)
ALKERMES PHARMA IRELAND)
LIMITED,)
)
Plaintiffs,)
)
)
v.) C.A. No. _____
)
ALKEM LABORATORIES LTD. and)
ASCEND LABORATORIES, LLC,)
)
Defendants.)

COMPLAINT

Acorda Therapeutics, Inc. (“Acorda”) and Alkermes Pharma Ireland Limited (“Alkermes” and together with Acorda, “Plaintiffs”), for their Complaint against Alkem Laboratories Ltd. and Ascend Laboratories, LLC (together, “Alkem” or “Defendants”), allege as follows:

NATURE OF THE ACTION

1. This is an action by Plaintiffs against Defendants for patent infringement of United States Patent Nos. 5,540,938 (the ““938 patent”), 8,007,826 (the ““826 patent”), 8,354,437 (the ““437 patent”), 8,440,703 (the ““703 patent”) and 8,663,685 (the ““685 patent”) (collectively, the “Ampyra® Patents”).
2. This action arises out of Defendants’ filing of Abbreviated New Drug Application (“ANDA”) No. 206765 seeking approval by the United States Food and Drug Administration (“FDA”) to sell generic copies of Acorda’s flagship drug product Ampyra®, prior to the expiration of the Ampyra® Patents.

THE PARTIES

3. Acorda is a corporation organized under the laws of the State of Delaware and has its principal place of business located at 420 Saw Mill River Road, Ardsley, New York 10502. Acorda is engaged in the research, development, and sale of biotech and pharmaceutical products. Acorda invests extensively in designing and developing new and innovative therapies to restore neurological function and improve the lives of people with multiple sclerosis ("MS"), spinal cord injuries and other disorders of the nervous system. Ampyra® is the only treatment shown to improve walking in people with MS, which was demonstrated by an increase in walking speed.

4. Alkermes is an Irish corporation (company number 448848) having a principal place of business at Connaught House, 1 Burlington Road, Dublin 4, Ireland.

5. Alkermes is the assignee of the '938 patent. Acorda is the exclusive licensee in the U.S. to package, use, import, export, promote, distribute, offer for sale, sell and otherwise exploit the '938 patent for oral prescription medicine for the treatment of MS in humans. Acorda also has the right to initiate and prosecute legal action for infringement by a third-party of the '938 patent.

6. Acorda has all right, title, and interest in the '826 patent, '437 patent, '703 patent, and '685 patent, and the right to sue for infringement thereof.

7. On information and belief, defendant Alkem Laboratories Ltd. is a corporation organized and existing under the laws of the India, having its principal place of business at Alkem House, Devashish, Senapati Bapat Marg, Lower Parel (West), Mumbai 400013, Maharashtra, India.

8. On information and belief, Alkem Laboratories Ltd. develops, formulates, manufactures, markets, and sells pharmaceutical drug products, including generic drug products,

throughout the United States including in Delaware, through various directly- or indirectly-owned operating subsidiaries, including its wholly-owned subsidiary Ascend Laboratories, LLC.

9. On information and belief, defendant Ascend Laboratories, LLC is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 180 Summit Ave., Suite 200, Montvale, New Jersey 07645. On information and belief, Ascend Laboratories, LLC is a wholly-owned subsidiary of Alkem Laboratories Ltd.

10. On information and belief, Ascend Laboratories, LLC is in the business of, among other things, formulating, developing, manufacturing, marketing, and selling generic copies of branded pharmaceutical products for the United States market, including in Delaware.

JURISDICTION AND VENUE

11. This action arises under the patent laws of the United States, Title 35, United States Code. The Court has subject matter jurisdiction over this action pursuant to the provisions of 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

12. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery, this Court has personal jurisdiction over the Defendants.

13. This Court has personal jurisdiction over Defendants by virtue of the fact that, *inter alia*, they have committed — or aided, abetted, induced, contributed to, or participated in the commission of — the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Acorda, a Delaware corporation, and to Alkermes.

14. This Court has personal jurisdiction over Alkem Laboratories Ltd. On information and belief Alkem Laboratories Ltd. regularly does or solicits business in Delaware, engages in other persistent courses of systematic conduct in Delaware, and/or derives substantial revenue from services or things used or consumed by Alkem Laboratories Ltd. or its affiliates

and agents, including Ascend Laboratories, LLC, in Delaware, demonstrating that Alkem Laboratories Ltd. has continuous contacts with Delaware.

15. On information and belief, Alkem Laboratories Ltd. is in the business of manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in the state of Delaware. On information and belief, Alkem Laboratories Ltd. directly or through its affiliates and agents (including Ascend Laboratories, LLC), formulates, manufactures, packages, markets, and/or sells pharmaceutical drug products, including generic drug products, throughout the United States and in Delaware.

16. On information and belief, Alkem Laboratories Ltd. has previously availed itself of this forum by submitting to the jurisdiction of this Court and asserting counterclaims in other civil actions initiated in this jurisdiction, including, for example, *Sanofi, et al. v. Alkem Laboratories Ltd., et al.* (1:14-cv-00292-RGA), *Pfizer, Inc., et al. v. Alkem Laboratories Ltd.* (1:13-cv-01110-GMS), and *Medicis Pharmaceutical Corp. v. Alkem Laboratories Ltd.* (1:12-cv-01663-LPS).

17. This Court has personal jurisdiction over Ascend Laboratories, LLC. On information and belief, Ascend Laboratories, LLC regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed by Ascend Laboratories, LLC or its affiliates and agents, including Alkem Laboratories Ltd., in Delaware, demonstrating that Ascend Laboratories, LLC has continuous and systemic contacts with Delaware.

18. On information and belief, Ascend Laboratories, LLC is in the business of marketing, distributing, and selling pharmaceutical products, including generic pharmaceuticals

manufactured by Alkem Laboratories Ltd., throughout the United States, including in the state of Delaware.

19. On information and belief, Defendants are agents of each other and/or work in concert with each other with respect to the development, regulatory approval, marketing, sale, and distribution of pharmaceutical products throughout the United States, including into Delaware, including the dalfampridine extended release tablets described in Defendants' ANDA No. 206765 (the "Alkem Generic Tablets"), which are accused of infringing the Ampyra® Patents.

20. If ANDA No. 206765 is approved, the Alkem Generic Tablets will, among other things, be marketed and distributed in Delaware, and/or prescribed by physicians practicing and dispensed by pharmacies located within Delaware, all of which will have a substantial effect on Delaware. On information and belief, if ANDA No. 206765 is approved, Defendants will sell Alkem Generic Tablets in the state of Delaware and Ascend Laboratories, LLC will be involved in the sale, marketing, and/or distribution of the product.

21. Defendants know and intend that Alkem Generic Tablets will be distributed and sold in the United States, including in Delaware.

22. Alternatively, assuming that the above facts do not establish personal jurisdiction over Alkem Laboratories Ltd., this Court may exercise jurisdiction over Alkem Laboratories Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Alkem Laboratories Ltd. is a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) Alkem Laboratories Ltd. has sufficient contacts with the United States as a whole, including but not limited to manufacturing and selling generic

pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Alkem Laboratories Ltd. satisfies due process.

23. Venue is proper in this judicial district pursuant to the provisions of 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

The '938 Patent

24. On July 30, 1996, the United States Patent and Trademark Office (“USPTO”) issued the '938 patent, titled “Formulations and Their Use in the Treatment of Neurological Diseases.” The '938 patent is duly and legally assigned to Alkermes. Acorda is the exclusive licensee in the U.S. to package, use, import, export, promote, distribute, offer for sale, sell and otherwise exploit the '938 patent for oral prescription medicine for the treatment of MS in humans. Acorda also has the right to initiate and prosecute legal action for infringement by a third-party of the '938 patent. A copy of the '938 patent is attached hereto as Exhibit A.

The '826 Patent

25. On August 30, 2011, the USPTO issued the '826 patent, titled “Sustained Release Aminopyridine Composition.” The '826 patent is duly and legally assigned to Acorda. A copy of the '826 patent is attached hereto as Exhibit B.

The '437 Patent

26. On January 15, 2013, the USPTO issued the '437 patent, titled “Method of Using Sustained Release Aminopyridine Compositions.” The '437 patent is duly and legally assigned to Acorda. A copy of the '437 patent is attached hereto as Exhibit C.

The '703 Patent

27. On May 14, 2013, the USPTO issued the '703 patent, titled "Methods of Using Sustained Release Aminopyridine Compositions." The '703 patent is duly and legally assigned to Acorda. A copy of the '703 patent is attached hereto as Exhibit D.

The '685 Patent

28. On March 4, 2014, the USPTO issued the '685 patent, titled "Sustained Release Aminopyridine Composition." The '685 patent is duly and legally assigned to Acorda. A copy of the '685 patent is attached hereto as Exhibit E.

Orange Book Listing for Ampyra®

29. Acorda holds an approved New Drug Application ("NDA"), No. 022250, for the use of 10 mg dalfampridine extended release tablets to improve walking in patients with multiple sclerosis, which Acorda sells under the registered name Ampyra®.

30. The use of Ampyra® to improve walking in patients with MS is covered by the Ampyra® Patents.

31. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA has promulgated pursuant thereto, the Ampyra® Patents are listed in the FDA publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") for improvement of walking in patients with MS.

32. The Orange Book lists the expiration dates for the '938 patent as July 30, 2018, the '826 patent as May 26, 2027, the '437 patent as December 22, 2026, the '703 patent as April 8, 2025, and the '685 patent as January 18, 2025.

ALKEM'S ANDA

33. By letter dated July 2, 2014 (the "Alkem Notice Letter"), Alkem Laboratories Ltd. notified Plaintiffs that it had filed ANDA No. 206765 with the FDA, seeking approval under

the Federal Food, Drug and Cosmetic Act (“FDCA”) to market and sell Alkem Generic Tablets — generic copies of Ampyra® (10 mg dalfampridine extended release tablets) — to improve walking in patients with MS, prior to the expiration of the Ampyra® Patents.

34. The Alkem Notice Letter asserts that ANDA No. 206765 contains a “[P]aragraph IV” certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and that each claim of the Ampyra® Patents is “invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the [Alkem Generic Tablets].”

35. The Alkem Notice Letter also states that ANDA No. 206765 was submitted to the FDA and contains a Paragraph IV certification seeking to “obtain approval to engage in the commercial manufacture, use, or sale of dalfampridine, before the expiration of [the Ampyra® Patents].”

36. Upon information and belief, Defendants collaborated and acted in concert in the decision to file and the filing of ANDA No. 206765.

37. Upon information and belief, Defendants will distribute the Alkem Generic Tablets in the United States.

COUNT I
(Infringement of the '938 Patent)

38. The allegations of paragraphs 1-37 above are repeated and re-alleged as if set forth fully herein.

39. Pursuant to 35 U.S.C. § 271(e)(2)(A), Alkem’s filing of ANDA No. 206765 seeking approval to market Alkem Generic Tablets is an act of infringement of one or more claims of the '938 patent entitling Plaintiffs to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 206765 be a date which is not earlier than the expiration date of the '938 patent.

40. Alkem had knowledge of the '938 patent when it submitted ANDA No. 206765 to the FDA.

41. Upon information and belief, Alkem intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Alkem Generic Tablets with the proposed labeling. The use of Alkem Generic Tablets in accordance with and as directed by Alkem's proposed labeling would infringe one or more claims of the '938 patent.

42. Upon information and belief, Alkem intends to actively induce infringement of one or more claims of the '938 patent.

43. Upon information and belief, Alkem knows that Alkem Generic Tablets and the proposed labeling are especially made or adapted for use in infringing one or more claims of the '938 patent and that the ANDA Products and the proposed labeling are not suitable for any substantial noninfringing use.

44. Upon information and belief, Alkem intends to contribute to the infringement of one or more claims of the '938 patent.

45. The foregoing actions by Alkem constitute and/or would constitute infringement of one or more claims of the '938 patent, active inducement of infringement of one or more claims of the '938 patent, and/or contribution to the infringement by others of one or more claims of the '938 patent.

46. Plaintiffs will be substantially and irreparably harmed if Alkem is not enjoined from infringing the '938 patent. Plaintiffs' have no adequate remedy at law.

COUNT II
(Infringement of the '826 Patent)

47. The allegations of paragraphs 1-46 above are repeated and re-alleged as if set forth fully herein.

48. Pursuant to 35 U.S.C. § 271(e)(2)(A), Alkem's filing of ANDA No. 206765 seeking approval to market Alkem Generic Tablets is an act of infringement of one or more claims of the '826 patent entitling Acorda to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 206765 be a date which is not earlier than the expiration date of the '826 patent.

49. Alkem had knowledge of the '826 patent when it submitted ANDA No. 206765 to the FDA.

50. Upon information and belief, Alkem intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Alkem Generic Tablets with the proposed labeling. The use of Alkem Generic Tablets in accordance with and as directed by Alkem's proposed labeling would infringe one or more claims of the '826 patent.

51. Upon information and belief, Alkem intends to actively induce infringement of one or more claims of the '826 patent.

52. Upon information and belief, Alkem knows that Alkem Generic Tablets and the proposed labeling are especially made or adapted for use in infringing one or more claims of the '826 patent and that the ANDA Products and the proposed labeling are not suitable for any substantial noninfringing use.

53. Upon information and belief, Alkem intends to contribute to the infringement of one or more claims of the '826 patent.

54. The foregoing actions by Alkem constitute and/or would constitute infringement of one or more claims of the '826 patent, active inducement of infringement of one or more claims of the '826 patent, and/or contribution to the infringement by others of one or more claims of the '826 patent.

55. Acorda will be substantially and irreparably harmed if Alkem is not enjoined from infringing the '826 patent. Acorda has no adequate remedy at law.

COUNT III
(Infringement of the '437 Patent)

56. The allegations of paragraphs 1-55 above are repeated and re-alleged as if set forth fully herein.

57. Pursuant to 35 U.S.C. § 271(e)(2)(A), Alkem's filing of ANDA No. 206765 seeking approval to market Alkem Generic Tablets is an act of infringement of one or more claims of the '437 patent entitling Acorda to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 206765 be a date which is not earlier than the expiration date of the '437 patent.

58. Alkem had knowledge of the '437 patent when it submitted ANDA No. 206765 to the FDA.

59. Upon information and belief, Alkem intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Alkem Generic Tablets with the proposed labeling. The use of Alkem Generic Tablets in accordance with and as directed by Alkem's proposed labeling would infringe one or more claims of the '437 patent.

60. Upon information and belief, Alkem intends to actively induce infringement of one or more claims of the '437 patent.

61. Upon information and belief, Alkem knows that Alkem Generic Tablets and the proposed labeling are especially made or adapted for use in infringing one or more claims of the '437 patent and that the ANDA Products and the proposed labeling are not suitable for any substantial noninfringing use.

62. Upon information and belief, Alkem intends to contribute to the infringement of one or more claims of the '437 patent.

63. The foregoing actions by Alkem constitute and/or would constitute infringement of one or more claims of the '437 patent, active inducement of infringement of one or more claims of the '437 patent, and/or contribution to the infringement by others of one or more claims of the '437 patent.

64. Acorda will be substantially and irreparably harmed if Alkem is not enjoined from infringing the '437 patent. Acorda has no adequate remedy at law.

COUNT IV
(Infringement of the '703 Patent)

65. The allegations of paragraphs 1-64 above are repeated and re-alleged as if set forth fully herein.

66. Pursuant to 35 U.S.C. § 271(e)(2)(A), Alkem's filing of ANDA No. 206765 seeking approval to market Alkem Generic Tablets is an act of infringement of one or more claims of the '703 patent entitling Acorda to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 206765 be a date which is not earlier than the expiration date of the '703 patent.

67. Alkem had knowledge of the '703 patent when it submitted ANDA No. 206765 to the FDA.

68. Upon information and belief, Alkem intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Alkem Generic Tablets with the proposed labeling. The use of Alkem Generic Tablets in accordance with and as directed by Alkem's proposed labeling would infringe one or more claims of the '703 patent.

69. Upon information and belief, Alkem intends to actively induce infringement of one or more claims of the '703 patent.

70. Upon information and belief, Alkem knows that Alkem Generic Tablets and the proposed labeling are especially made or adapted for use in infringing one or more claims of the '703 patent and that the ANDA Products and the proposed labeling are not suitable for any substantial noninfringing use.

71. Upon information and belief, Alkem intends to contribute to the infringement of one or more claims of the '703 patent.

72. The foregoing actions by Alkem constitute and/or would constitute infringement of one or more claims of the '703 patent, active inducement of infringement of one or more claims of the '703 patent, and/or contribution to the infringement by others of one or more claims of the '703 patent.

73. Acorda will be substantially and irreparably harmed if Alkem is not enjoined from infringing the '703 patent. Acorda has no adequate remedy at law.

COUNT V
(Infringement of the '685 Patent)

74. The allegations of paragraphs 1-73 above are repeated and re-alleged as if set forth fully herein.

75. Pursuant to 35 U.S.C. § 271(e)(2)(A), Alkem's filing of ANDA No. 206765 seeking approval to market Alkem Generic Tablets is an act of infringement of one or more claims of the '685 patent entitling Acorda to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 206765 be a date which is not earlier than the expiration date of the '685 patent.

76. Alkem had knowledge of the '685 patent when it submitted ANDA No. 206765 to the FDA.

77. Upon information and belief, Alkem intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Alkem Generic Tablets with the proposed labeling. The use of Alkem Generic Tablets in accordance with and as directed by Alkem's proposed labeling would infringe one or more claims of the '685 patent.

78. Upon information and belief, Alkem intends to actively induce infringement of one or more claims of the '685 patent.

79. Upon information and belief, Alkem knows that Alkem Generic Tablets and the proposed labeling are especially made or adapted for use in infringing one or more claims of the '685 patent and that the ANDA Products and the proposed labeling are not suitable for any substantial noninfringing use.

80. Upon information and belief, Alkem intends to contribute to the infringement of one or more claims of the '685 patent.

81. The foregoing actions by Alkem constitute and/or would constitute infringement of one or more claims of the '685 patent, active inducement of infringement of one or more claims of the '685 patent, and/or contribution to the infringement by others of one or more claims of the '685 patent.

82. Acorda will be substantially and irreparably harmed if Alkem is not enjoined from infringing the '685 patent. Acorda has no adequate remedy at law.

COUNT VI
(Induced Infringement)

83. The allegations of paragraphs 1-82 above are repeated and re-alleged as if set forth fully herein.

84. On information and belief, Ascend Laboratories, LLC actively and knowingly caused to be submitted and/or assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 206765 to the FDA, knowing of the Ampiya® Patents.

85. The filing of the ANDA by Defendants through Alkem Laboratories Ltd. constituted direct infringement under 35 U.S.C. § 271(e). Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), defendant Ascend Laboratories, LLC induced the infringement of the Ampiya® Patents by actively and knowingly causing to be submitted and/or assisting with, participating in, contributing to, and/or directing the submission of ANDA No. 206765 to the FDA knowing that the submission of ANDA No. 206765 would constitute direct infringement of the Ampiya® Patents. Defendant Ascend Laboratories, LLC's knowing and purposeful activities causing to be submitted and/or assisting with, participating in, contributing to, and/or directing the filing of ANDA No. 206765, knowing that its submission would constitute direct infringement, constitute induced infringement of the Ampiya® Patents.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

- A. A judgment that Alkem's submission of ANDA No. 206765 was an act of infringement and that Alkem's making, using, offering to sell, selling or importing Alkem Generic Tablets prior to the expiration of the Ampiya® Patents will infringe, actively induce infringement and/or contribute to the infringement of each of the Ampiya® Patents;
- B. A judgment that defendant Ascend Laboratories, LLC's knowing and purposeful activities causing to be submitted and/or assisting with, participating in, contributing to, and/or directing the filing of ANDA No. 206765, knowing that its

submission would constitute direct infringement, induced infringement of each of the Ampyra® Patents;

- C. A judgment that the effective date of any FDA approval for Alkem to make, use offer for sale, sell, market, distribute, or import the Alkem Generic Tablets be no earlier than the dates on which the Ampyra® Patents expire, or any later expiration of exclusivity to which Plaintiffs are or become entitled;
- D. A permanent injunction enjoining Alkem, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making using, selling, offering for sale, marketing, distributing, or importing the Alkem Generic Tablets, and from inducing or contributing to any of the foregoing, prior to the expiration of the Ampyra® Patents, or any later expiration of exclusivity to which Plaintiffs are or become entitled;
- E. A judgment that this case is an exceptional case under 35 U.S.C. § 285, entitling Plaintiffs to an award of its reasonable attorneys' fees for bringing and prosecuting this action;
- F. An award of Plaintiffs' costs and expenses in this action;
- G. Such further and additional relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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